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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,524	12/29/2003	Richard E. Parizek	1 1995.184 US D1	8568

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/748,524	PARIZEK ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,11,15,17-19,40,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,11, 15, 17-19, 40, 46-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/25/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed July 25, 2005 has been entered. The amendment to the specification has been entered. Claims 1-3,18-19 and 40 have been amended. Claims 4-10, 12-14, 16, 20-39 and 41-45 have been cancelled. Claims 1-3, 11, 15, 17-19, 40 and 46-47 are under consideration in this office action.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

a) The rejection of claims 3, 5, and 31 under 35 U.S.C. 112, second paragraph;

b) The rejection of claims 1-6, 11, 15, 17-19, 28-29, 33, 40 and 46-47 under 35 U.S.C. 103(a) as being unpatentable over Animal Pharm 203 p28 in view of Vision Vaccines; and

c) The double patenting rejection of claims 1-6, 11, 15,17-19, 28-29, 33, 40 and 46-47 under the judicially created doctrine of double patenting.

Response to Arguments

3. Applicant's arguments filed July 25, 2005 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. The rejection of claims 1-3,11, 15, 17-19 and 40 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The rejection was on the grounds that Roberts teach a multicomponent vaccine for ruminants comprising an immunologically effective combination of a protective antigen component from at least six or seven specifically recited clostridial organisms, a protective antigen from at least one non-clostridial gram-negative *M. bovis and/or H. somnus*, and the specifically recited adjuvant wherein the dose is 2 ml or less.

Applicants' assert that Roberts does not provide an enabling disclosure for the ordinarily skilled practitioner to prepare the vaccines as presently claimed. However applicant is reminded that enablement is not the issue since the instant claims are not drawn to a method of vaccine preparation. Rather the issue is whether Roberts teaches a multicomponent clostridial vaccine comprising clostridial bacterins or toxoids derived from each of *Clostridium chauvoei, Clostridium septicum, Clostridium novyi, Clostridium sordellii, Clostridium perfringens,* Type C and Type D and a saponin adjuvant and a non-clostridial antigens which is *Moraxella bovis*, at a doses of about 2ml or less; and Roberts does. Therefore applicants' argument is not persuasive.

Applicants urge that because Roberts's examples are 5ml, Roberts does not teach the instant claims. However the MPEP section 2123 teaches that patents are relevant as prior art for all they contain, "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir.1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed."). If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967). In the instant case, Roberts may be relied upon because it reasonably suggest to one having ordinary skill the art multicomponent vaccines administered in a low dose volume of about 2 ml or less. Roberts does not have to use each embodiment in a example to teach the effective dosage level. Furthermore, while applicants argue about Roberts not teaching examples comprising fewer than 5ml, applicant is reminded that applicants' own disclosure fails to show

examples of a multicomponent clostridial vaccine comprising the non-clostridial *M .bovis* protective antigen wherein the vaccine is in a low dose volume of about 2 ml or less. Nor does applicants' specification show examples of a multicomponent clostridial vaccine comprising non-clostridial *M. bovis* and *H. somnus* protective antigens wherein the vaccine is in a low dose volume of about 2 ml or less. Rather applicants' specification merely mentions the possibility of having multicomponent clostridial vaccines combined with other antigens and mentions the possibility of having low dose volumes of vaccines. Therefore applicants' argument is not persuasive.

Furthermore, M.P.E.P .2131.03 [R-2] entitled *Anticipation of Ranges* states that when the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, yet the prior art discloses the claimed range with sufficient specificity, then the prior art anticipates the claims. The disclosure of Roberts dosage of 1 to 5 ml and as low as 0.5ml would allow one of ordinary skill in the art to clearly envisage the instant claims range of about 2ml or less. Thus, contrary to applicants' statements about Roberts theoretical teaching of low does volumes, Roberts clearly states with sufficient specificity low dose volume containing multicomponent vaccines just as required by the instant claims.

Applicants' point to publications describing cost, injection site lesions and market takeovers. However evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to 35 U.S.C. 102 rejections and thus cannot overcome a rejection so based. *In re Wiggins*, 488 F.2d 538, 543, 179 USPQ 421, 425

(CCPA 1973). Therefore applicants' assertions are not persuasive and the rejection is maintained.

5. The rejection of claims 46-47 under 35 U.S.C. 102(a) as being anticipated by Roberts (WO 94/22476) is maintained for reasons already of record. The rejection was on the grounds that Roberts teach are a method of immunizing a bovine animal comprising administering an effective amount of the vaccine in claims 1 or 2, just as instantly claimed. However, for the reasons set forth above the rejection of claims 46 and 47 is maintained.

New Grounds of Objection and Rejection

Claim Objections

6. Claim 3 is objected to because of the following informalities: Claim 3 recites "*Clostridium h/aemolyticum*". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Acronyms like *H. somnus* must be spelled out when used for the first time in a chain of claims.

Conclusion

8. No claims allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
October 5, 2005

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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